

REMARKS

The Examiner is thanked for graciously holding a telephone interview with the undersigned on April 3, 2006. The Office Action and the specification are discussed. It was agreed that claim 1 will be amended that further consideration be given to the amended claim 1 in view of the fact that the claimed powder for oral suspension possess superior property of stabilizing non-dihydrate azithromycin forms in the presence of a form conversion enhancer.

Claims 1-78 were pending in the present application. Applicants have canceled claims 2, 8, 12-15, 18, 19 and 29-78 without prejudice and amended claims 1 to clarify that the claimed powder for oral suspension comprises non-dihydrate azithromycin, an azithromycin form conversion stabilizing excipient; and an azithromycin form conversion enhancer. Applicants have also amended claims 7, 9, 16, 20, 23 and 26 to correct informalities and change claim dependency and these amendments do not raise any issue of new matter. Support for the amendments to claim 1 can be found, , on page 3, lines 18-22, page 19, lines 20-24 of the original specification and in the original claim 8. Applicants contend that the present Amendment is fully supported by the original specification and does not raise any issue of new matter. Therefore, entry of the present Amendment is respectfully requested. Upon entry of the present Amendment, claims 1, 7, 9-11, 16, 17 and 20-28 will be under examination.

CLAIM OBJECTIONS

Claims 20, 23 and 26 stand objected to as being in improper form.

Applicants have amended claims 20, 23 and 26 to be dependent only upon claim 1. Therefore, this ground of objection is moot.

OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTION

Claims 1, 7-11 and 16-28 stand rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1-2 of U.S. Patent No. 6,861,413 (hereinafter "the '413 patent")

Applicants respectfully point out that claim 1, as amended, and its dependent claims are directed to powders for oral suspension comprises non-dihydrate azithromycin, an

azithromycin form conversion (emphasis added) stabilizing excipient; and an azithromycin form conversion enhancer. Such powders are patentably distinctive from claims 1-2 of the '413 patent. Therefore, this ground of rejection is moot. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

CLAIM REJECTION UNDER 35 U.S.C. 103(a) AND 102(e), (f) AND/OR (g)

Claims 1, 7-11 and 16-28 stand rejected as allegedly being directed to an invention not patentably distinctive from claims 1 and 2 of the '413 patent.

Applicants respectfully disagree with this ground of rejection as claim 1, as amended, and its dependent claims are directed to powders for oral suspension comprises non-dihydrate azithromycin, an azithromycin form conversion stabilizing excipient; and an azithromycin form conversion enhancer. Such powders are patentably distinctive from claims 1-2 of the '413 patent. Therefore, this ground of rejection is moot.

OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTION

Claims 1, 7-10, 16-20, 23 and 26 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1, 3 and 4 of co-pending Application No. 10/355,575 (hereinafter "the '575 application").

Applicants respectfully disagree with this ground of rejection because claim 1, as amended, and its dependent claims are directed to powders for oral suspension comprises non-dihydrate azithromycin, an azithromycin form conversion stabilizing excipient; and an azithromycin form conversion enhancer. Such powders are patentably distinctive from claims 1, 3 and 4 of the '575 application. Therefore, this ground of rejection is moot. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTION

Claims 1, 7-10, 16-20, 23 and 26 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 15-37 of co-pending Application No. 10/327,383 (hereinafter "the '383 application").

Applicants respectfully request that this ground of rejection be withdrawn for the same reasons as stated in Applicants' response to the double patenting rejection over the '575 application because the claim 1, as amended, and its dependent claims are directed to

powders for oral suspension comprises non-dihydrate azithromycin, an azithromycin form conversion stabilizing excipient; and an azithromycin form conversion enhancer and are patentable distinctive from claims 15-37 of the '383 application.

CLAIM REJECTION UNDER 35 U.S.C. 102(b)

Claims 1, 7-10 and 16-19 stand rejected as allegedly being anticipated by Curatolo et al., EP 679 400 (hereinafter "Curatolo").

Applicants respectfully disagree with this ground of rejection as Curatolo does not teach each and every element of the amended claim 1 and its dependent claims. Applicants note that the amended claim 1 is directed to powders for oral suspension comprises non-dihydrate azithromycin, an azithromycin form conversion stabilizing excipient; and an azithromycin form conversion enhancer. In addition, claims 7-10, 16-20, 23 and 26 are dependent upon the amended claim 1 and incorporate all its elements. Therefore, this ground of rejection is obviated by the amendments to claim 1. Accordingly, reconsideration and withdrawal of this ground of rejection are respectfully requested.

CLAIM REJECTION UNDER 35 U.S.C. 102(e)

Claims 1, 7-10, 16-21, 23 and 24 stand rejected as allegedly being anticipated by Tenengauzer et al., U.S. Patent No. 6,764,997(hereinafter "Tenengauzer").

Applicants respectfully disagree with this ground of rejection as Tenengauzer does not disclose each and every element of the amended claim 1 and its dependent claims. Specifically, the amended claim 1 is directed to powders for oral suspension comprises non-dihydrate azithromycin, an azithromycin form conversion stabilizing excipient; and an azithromycin form conversion enhancer while Tenengauzer disclosed the use anti-oxidant to prevent degradation of azithromycin (see for example, claim 2 of Tenengauzer). Therefore, Tenengauzer does not anticipate the amended claim 1 as well as all its dependent claims. Accordingly, reconsideration and withdrawal of this ground of rejection are respectfully requested.

CLAIM REJECTION UNDER 35 U.S.C. 103(a)

Claims 20, 21, 23 and 24 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Curatolo, in view of either Tenengauzer or Li et al., U.S. Patent No.

6,977,243 (hereinafter “Li”).

Applicants respectfully point out that the subject matter of the amended claim 1 relates to the prevention of form conversion and none of the cited references, either alone or in combination, disclose such prevention of form conversion. Applicants contend that the combinations of Curatolo and Tenengauzer or Curatolo and Li would not render the amended claim 1 obvious because the combination does not teach form stabilization. Applicants note that claims 20, 21, 23 and 24 are dependent upon claim 1, as amended, and incorporate all its elements. Therefore, claims 20, 21, 23 and 24 are nonobvious over Curatolo, in view of either Tenengauzer or Li. Accordingly, reconsideration and withdrawal of this ground of rejection are respectfully requested.

CLAIM REJECTION UNDER 35 U.S.C. 103(a)

Claims 21 and 22 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Curatolo, in view of either Tenengauzer or Li as applied to claim 20, and further in view of Schwarz et al., WO 2004/000865 (hereinafter “Schwarz”).

For the same reasons as stated in Applicants’ response to obviousness rejection of claims 20, 21, 23 and 24, claims 21 and 22 are nonobvious over Curatolo, in view of either Tenengauzer or Li, and further in view of Schwarz as these combinations do not teach form stabilization. Accordingly, reconsideration and withdrawal of this ground of rejection are respectfully requested.

CLAIM REJECTION UNDER 35 U.S.C. 103(a)

Claims 24 and 25 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Curatolo, in view of Singer et al., U.S. Patent No. 6,365,574 (hereinafter “Singer”) as applied to claim 23, and further in view of Schwarz.

For the same reasons as stated in Applicants’ response to obviousness rejection of claims 20, 21, 23 and 24, claims 24 and 25 are nonobvious over Curatolo, in view of Singer, and further in view of Schwarz as these combinations do not teach form stabilization. Accordingly, reconsideration and withdrawal of this ground of rejection are respectfully requested.

CLAIM REJECTION UNDER 35 U.S.C. 103(a)

Claims 27 and 28 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Curatolo, in view of Karimian et al., U.S. Patent No. 6,245,903 (hereinafter “Karimian”) as applied to claim 26, and further in view of Schwarz.

For the same reasons as stated in Applicants’ response to obviousness rejection of claims 20, 21, 23 and 24, claims 27 and 28 are nonobvious over Curatolo, in view of Karimian, and further in view of Schwarz as these combinations do not teach form stabilization. Accordingly, reconsideration and withdrawal of this ground of rejection are respectfully requested.

CLAIM REJECTION UNDER 35 U.S.C. 103(a)

Claim 11 stands rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Curatolo, in view of Artman et al., U.S. Patent No. 6,383,527 (hereinafter “Artman”).

For the same reasons as stated in Applicants’ response to obviousness rejection of claims 20, 21, 23 and 24, claim 11 is nonobvious over Curatolo, in view of Artman as the Curatolo-Artman combination does not teach form stabilization. Accordingly, reconsideration and withdrawal of this ground of rejection are respectfully requested.

CONCLUSION

In view of the claim amendments and the remarks, further and favorable consideration of all currently pending claims is respectfully requested.

It is believed that no fee is deemed necessary in connection with the filing of the present Amendment. However, if any fees are required, the Commissioner is hereby authorized to charge any such fees to our Deposit Account No. 16-1445.

Respectfully submitted,

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